

REMARKS

A first non-final Office Action mailed August 26, 2003 has been received and carefully reviewed. Claims 1-63 are pending in the application.

Original claims 1, 2, 5-12, 15-22, 26, 27, 30-42, and 44-63 have been rejected. Original claims 3, 4, 13, 14, 23-25, 28, 29 and 43 have been objected to, but would be allowable if rewritten in independent form. Claims 47-50 have been amended for reasons not related to patentability. Moreover, the amendments to claims 47-50 do not have a narrowing effect. Reconsideration of the application as amended and withdrawal of the claim rejections are respectfully requested in view of the following remarks.

Claims 1, 2, 5-12, 15-22, 26, 27, 30-42, 44-63 were rejected under 35 U.S.C. 103 (a) as being unpatentable over *White* (US Patent 5,999,851) in view of *Thompson* (US Patent 6,453,195).

Applicant respectfully contends that the combination of *White* and *Thompson* does not render Applicant's pending claims obvious. In the Office Action, the Examiner contends that *White* teaches all of the subject matter of the rejected claims except the use of drugs to be administered to a patient when the patient perceives symptoms of arrhythmia. *Thompson* is relied on for supplying the elements missing in the *White* teachings.

Respectfully, *White* fails to teach several features of Applicant's claims, in addition to the drug administration elements acknowledged by the Examiner. *White* discloses an atrial defibrillation system having patient selectable atrial fibrillation detection. *White* does not disclose a system for delivering a pacing regimen as is contemplated in the pending claims.

Thompson teaches an external drug delivery device wirelessly coupled to an implantable atrial cardioverter system. As with *White*, *Thompson* is directed to delivery of cardioversion and defibrillation therapies to treat tachyarrhythmia of

the atria. *Thompson* does not disclose a system for delivering a pacing regimen as is contemplated in the pending claims.

The asserted combination further fails to teach or suggest generating a perceivable initiating signal instructing the patient or a physician to commence with a drug delivery regimen to treat an actual cardiac arrhythmic condition. As discussed previously, *White* does not contemplate drug administration.

Thompson teaches administering pain reducing drugs or agents, threshold reducing agents or blood pressure regularizing agents, such as those identified by the Examiner at column 11, line 44 through column 12, line 30 of *Thompson*.

To establish *prima facie* obviousness of a claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (see, e.g., MPEP § 2142).

Respectfully, the combination of *White* and *Thompson* fails to teach or suggest all of the claim limitations recited in Applicant's rejected claims. The asserted combination does not teach or suggest delivering a pacing regimen as is contemplated in the pending claims. For example, neither *White* nor *Thompson*, alone or in combination, teaches or suggests initiating a pacing regimen to treat an actual cardiac arrhythmic condition or a non-arrhythmic cardiac condition as is presently claimed. The asserted combination neither teaches nor suggests initiating a safe mode of pacing appropriate for an adverse cardiac condition as is presently claimed. Moreover, the combination of *White* and *Thompson* fails to teach or suggest initiating a pacing regimen that accounts

for presence of a drug delivered to the patient as part of the drug delivery regimen as is presently claimed.

Moreover, the asserted combination fails to teach or suggest generating, by a non-implanted activator in communication with an implanted medical device, a perceivable initiating signal instructing the patient or a physician to commence with a drug delivery regimen to treat an actual cardiac arrhythmic condition. *Thompson* merely teaches administering a pain relieving drug to reduce the pain associated with atrial defibrillation therapy, but wholly fails to disclose delivering a drug regime to treat a cardiac arrhythmic condition, such as one that includes an anti-arrhythmic drug, for example.

Applicant respectfully asserts that the requisite suggestion or motivation to modify *White* in view of *Thompson* or to combine the teachings of *White* and *Thompson* can not be found in the references themselves. For example, *White* is directed to an atrial fibrillation system having patient selectable atrial fibrillation detection, but fails to teach drug administration and pacing regimens to address adverse cardiac conditions as is contemplated in Applicant's claims. One skilled in the art would not be motivated to combine a reference, such as *Thompson*, that is primarily directed to atrial fibrillation treatment and delivery of pain reducing drugs with the teachings of *White* in a manner suggested in the Office Action. Moreover, there is no reasonable expectation that, given the teachings or suggestions of *White* and *Thompson*, one skilled in the art could successfully arrive at Applicant's claimed subject matter, absent resorting to hindsight reconstruction.

It is a requirement that actual evidence of a suggestion, teaching or motivation to combine prior art references be shown, and that this evidence be "clear and particular." *In re Dembiczaik*, 50 USPQ2d 1614 (Fed. Cir. 1999). Broad conclusory statements regarding the teaching of references, standing alone, are not evidence. *Id.*

Because the combination of *White* and *Thompson* fails to teach or suggest several of the above-identified features of claims 1, 2, 5-12, 15-22, 26, 27, 30-42, and 44-63, and because no motivation or suggestion to combine these reference teachings can be identified in the references themselves, and further because the asserted combination does not provide a sufficient basis to support a reasonable expectation of success, Applicant respectfully asserts that the Examiner has failed to establish *prima facie* obviousness of Applicant's subject matter recited in 1, 2, 5-12, 15-22, 26, 27, 30-42, and 44-63.

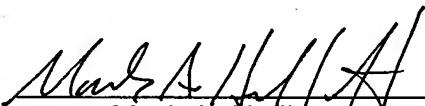
Without acquiescing to the Examiner's characterization of the relied-on references as they have been applied to Applicant's dependent claims, Applicant believes it unnecessary to address all grounds for rejection of every dependent claim in view of the clear grounds for patentability of the claims from which they respectively depend. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending there from is nonobvious." M.P.E.P. §2143.03; citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). Applicant, however, reserves the right to address these rejections should the Examiner maintain the rejection of the base claims, notwithstanding Applicant's remarks presented hereinabove.

Appl. Serial No. 10/017,941
Docket No.: GUID.002US01
Amendment and Response

It is believed that claims 1-63 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,
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Date: November 25, 2003

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Background

The Office is in the process of implementing an electronic image capture system to replace the standard paper processing of patent applications. Documents formerly placed in the paper file wrapper of pending patent applications (including the specification, oath or declaration, drawings, references, amendments, Office actions, foreign patent documents and non-patent literature of information disclosure statements and file jacket notations) are being electronically scanned and loaded into the Image File Wrapper (IFW) system. Once documents are loaded into the IFW system, examiners, technical support staff, other USPTO staff, and contractors will perform further processing and examination using the IFW system. *See Notification of United States Patent and Trademark Office Patent Application Records being Stored and Processed in Electronic Form, 1271 Off. Gaz. Pat. Office 100 (June 17, 2003).*

PART 1. Central Delivery of Hand-Carried Patent Application Related Papers

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